



Declaration why Pugh's disclosed device will not work with small sample volumes as currently claimed

I, Tom Xu, with a Ph. D. degree in Medicinal Chemistry, with more than 20 years of experience in clinical diagnostic field, and an active member of American Association of Clinical Chemistry, make the following statements:

Pugh's invention, US Patent 5,736,103, (The '103 patent) addresses sample cross contamination issues. The frustum-shaped design is primarily configured to accommodate the excess sample dripping, as is noted in the written description, "[s]ince contamination is possible if excess sample were to drop from the disposable" (column 6, lines 29-30). As shown in Figs. 11-15 and Fig 18 of the '103 patent, this kind of design require at least 10-50 microliters of sample to reach the membrane for an accurate measurement for the analyte, as commonly seen from the Assignee Lifescan's photometric meters and strips on the blood glucose market. Therefore, it is impossible for Pugh to use a 0.1-0.5 microliter sample to do a meaningful test. Pugh's device will fail if used with the sample volumes as claimed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10/18/2006

Tom Xu